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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/709,246

04/23/2004

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101896-0242 (DEP5294)

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21125 7590 12/28/2009  
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EXAMINER

FISHER, ELANA BETH

ART UNIT

PAPER NUMBER

3733

NOTIFICATION DATE

DELIVERY MODE

12/28/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/709,246 | <b>Applicant(s)</b><br>BOOMER ET AL. |  |
|                              | <b>Examiner</b><br>ELANA B. FISHER   | <b>Art Unit</b><br>3733              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3**

10709246 - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-10 and 13-25 is/are pending in the application.
- 4a) Of the above claim(s) 7-10,20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6,13-19 and 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 5, 2009 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to claims 1 and 23 stating "the inferior and superior surfaces are configured to taper away from one another toward the first end along an entire length thereof from the recess to the first end when the locking mechanism is disposed *and fully distally inserted* in the bore..." (emphasis added) is not supported by the original disclosure. In the submitted amendment, applicant provides paragraphs [0047]-[0050] and figures 1B, 1C, and 1E in the disclosure as support. However, in neither of these, nor throughout the remainder of the disclosure, is anything provided to even suggest that when the locking mechanism is fully within

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the bore of the clamp member, the inferior and superior surfaces taper away from one another. In the portions of the disclosure pointed to by applicant, the surfaces are either parallel or touching one another.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 4-6, 13-15, and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Morrison (U.S. Patent 6,872,209).

Morrison et al. disclose an implantable spinal connector for mating a spinal fixation element to a spinal anchoring device, comprising: a clamp member (103) having top and bottom portions (109, 108) with a recess (107) formed there between, the top and bottom portions including first and second ends (see diagram provided), the second ends being connected to one another such that the top and bottom portions are a singular piece and are movable between an open position (FIG 42) in which the top and bottom portions are spaced a distance apart from one another, and a closed position (FIG 34) in which the clamp member is adapted to engage a spinal fixation element (B) disposed within the recess (107). The top and bottom portions including inferior (103.1) and superior (103.2) surfaces, respectively, which extend from the recess (107) to the first end (FIG 42). The clamp member further including a bore (117, 118) located between the recess and the

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first end and extending through the top and bottom portions for receiving a locking mechanism (80) for locking the top and bottom portions in the closed position (FIG 34). The bore (117, 118) includes a threaded (115c) portion in at least one of the top and bottom (118) portions for mating with corresponding threads formed on at least a portion of the locking mechanism (FIG 36). Furthermore, the inferior and superior surfaces (103.1, 103.2) are configured to taper away from one another toward the first end along an entire length thereof from the recess (107) to the first end when the locking mechanism is disposed and fully distally inserted in the bore extending through the top and bottom portions (FIG 34; FIG 36). Additionally, the top and bottom portions are biased to the open position (FIG 42) such that a force greater than the biasing force must be applied to move the top and bottom portions to the closed position.

Moreover, the recess (107) has a concave shape and is formed in each of the inferior surface of the top portion and the superior surface of the bottom portion of the clamp member (FIG 42). Additionally, there is a locking mechanism (80) disposable through the bore (117, 118) and effective to lock the top and bottom portions in the closed position to retain a spinal fixation element there between (FIG 34), wherein the locking mechanism (80) comprises a fastening element having a head (82) and a shaft (84), and wherein one of the bore formed in the top portion and the bore formed in the bottom portion of the clamp member is adapted to freely rotatably receive the threaded shaft of the fastening element, and the other one of the bore formed in the top portion and the bore formed in the bottom portion is internally threaded to mate to threads formed on at least a portion of the shaft of the fastening element (FIG 36). Further, the fastening

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element includes a flange (86) formed there around and adapted to at least temporarily mate the fastening element to a spinal anchoring device. Morrison further teaches that the clamp member (103) is formed from a material that allows the clamp member to deform around a spinal fixation element disposed between the top and bottom portions when the clamp member is locked in the closed position (Column 8, lines 1-4).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 16-19 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (U.S. Patent 6,872,209).

Morrison discloses a connector according to claim 14 and 24 above, and additionally discloses that the fastening element (80) including a mating element in the form of a socket formed on a distal-most end thereof for mating with a driver tool (FIG 36). However, Morrison fails to disclose that the threads in the bore (115c) are located in the top portion (117) of the bore. It would have been obvious to one skilled in the art to modify the clamp taught by Morrison to have the threads extend to the top portion of the bore, since it would provide controlled entry of the fastening element into the bore at an earlier time than that currently provided.

Additionally, Morrison fails to disclose that the threads in the bore and on the shaft are left-handed threads. It would have been an obvious matter of design choice to

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one skilled in the art at the time the invention was made to have left-handed threads, since it is a configuration a person of ordinary skill in the art would find obvious for the purpose of providing threads. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

### ***Response to Arguments***

8. Applicant's arguments filed October 5, 2009 have been fully considered but they are not persuasive.

With regards to applicant's arguments that the Morrison reference does not teach the subject-matter in the amended claims, examiner respectfully disagrees. Applicant referenced specific language stating that the embodiment shown in figures 34-42 (the one referenced above) was "similar" to the original embodiment. Therefore applicant assumed that the inferior and superior surfaces do not taper away from one another when the locking mechanism is fully within the bore. However, figure 34 does show the feature required by the claim language. This is confirmed in figure 36, which shows the locking mechanism (80) fully within the bore. According to Column 3, lines 40-41, figure 36 is merely a different view of the apparatus shown in figure 34. Therefore, the clamp taught by Morrison does read on the claim language.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELANA B. FISHER whose telephone number is (571)270-3643. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elana B Fisher/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733